

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

**IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Thomas I. Vanaskie (Ret.),
Magistrate Judge

DECLARATION OF DR. MIN LI

1. I am Vice President of Analytic Operations for Zhejiang Huahai Pharmaceutical Co., Ltd. (“ZHP”), with responsibility for overseeing company-wide analytical research and development, and providing technical leadership in the company’s API quality control operations. I submit this declaration in support of the motion to seal certain confidential documents filed by Defendants ZHP, Princeton Pharmaceutical Inc. (“Princeton”) and Huahai U.S. Inc. (“Huahai U.S.”).

2. I understand that the ZHP Parties seek to seal an email by a ZHP employee, Jinsheng Lin, dated July 27, 2017 (the “July 27, 2017 email”) that was sent to me, as well as portions of my deposition testimony that discuss the contents of the July 27, 2017 email.

3. I received the July 27, 2017 email and state that I have reviewed the July 27, 2017 email, as well as the portions of my April 20, 2021 deposition testimony identified by Plaintiffs at page and line cites 84:3-107:14, and that this declaration is made on the basis of my personal knowledge.

4. The July 27, 2017 email, which was internal to the ZHP Parties and not intended for dissemination outside the ZHP Parties, concerns the results of a preliminary investigation by

ZHP's technical analysis department (CEMAT) into certain technical changes observed during the attempted process improvements for the manufacture of irbesartan API.

5. The preliminary investigation and test results described in the July 27, 2017 email were part of a concerted project by the ZHP Parties to improve its manufacturing processes for irbesartan API.

6. Specifically, the July 27, 2017 email focuses on proprietary technical improvements that were tested by the Chuannan facility's Technical Department, the Technical Department's communications with CEMAT regarding certain technical changes observed during the process improvements, and CEMAT's analysis for an unknown impurity observed during the attempted process improvement of irbesartan API.

7. The July 27, 2017 email also proposes additional testing by CEMAT to simulate the processes attempted by the Technical Department and resulting conditions, and to monitor and verify the test results.

8. The information disclosed in the July 27, 2017 email is highly confidential, proprietary, and competitively sensitive because it reveals how the ZHP Parties sought to optimize their procedures for manufacturing irbesartan API by addressing certain technical process changes, and the specific tests conducted by CEMAT to investigate these changes. These actions were the result of significant research and development by ZHP and have not been disseminated outside of the company.

9. The information disclosed in the July 27, 2017 email would be of significant competitive value to ZHP's competitors because it would disclose the ZHP Parties' API process optimization efforts and related testing methods, as well as the related and proprietary research

and development activities of CEMAT. Details of ZHP's API processes and testing methods are highly sensitive and important proprietary commercial information.

10. Disclosure of ZHP's API process optimization strategies and testing methods to ZHP's direct competitors would result in significant competitive harm to the ZHP Parties. The ZHP Parties are already competitively disadvantaged as a result of the FDA's prohibition on ZHP's exporting its products into the U.S. market. Disclosure of ZHP's confidential information would allow ZHP's direct competitors to benefit from and implement ZHP's proprietary research and development information while the ZHP Parties are absent from the U.S. market, awarding a significant competitive advantage to the ZHP Parties' competitors. Furthermore, such disclosure would critically impede the ZHP Parties' ability to re-enter the U.S. market and to compete effectively in the highly competitive generic pharmaceutical marketplace following the removal of the current import ban affecting ZHP's API and finished dose products.

I DECLARE UNDER PENALTY OF PERJURY UNDER THE LAWS OF THE UNITED STATES THAT TO THE BEST OF MY KNOWLEDGE THE FOREGOING IS TRUE AND CORRECT.

Executed on November 6, 2021 in Linhai (city), China (state).



, Declarant